

Applicant(s): B. Silverman
Application No.: 10/620,919
Examiner: Michael J. Araj

Remarks

Claims 1, 3-5, 7, 10, 11, and 13-26 are pending in the application and are presented for the Examiner's review and consideration. Claims 1, 7, 10, 11, 17, and 26 has been amended and claims 2, 6, 8, 9, and 12 have been cancelled. Applicant believes the claim amendments, cancellations, and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Election/Restriction

Applicant affirms the election of Group I of the bone plate and Group I of the transverse member.

Specification

Applicant has amended the title as suggested by the Examiner.

35 U.S.C. § 101 Rejection

Claims 2 and 6-12 were rejected under 35 U.S.C. § 101 as being drawn to non-statutory subject matter. In particular, the Examiner asserted that these claims positively recite part of a human. As an initial matter, Applicant has cancelled claims 2 and 6, rendering the rejection of these claims moot. Furthermore, claim 1 has been amended and Applicant submits that as amended claim 1 does not include a human within its scope.

35 U.S.C. § 102(b) Rejection

Claims 1-12, 17-21 and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,693,616 to Roaf ("Roaf"). For the reasons set forth below, Applicant respectfully submits that the rejected claims are patentable over Roaf.

Each and every claim as originally filed recited "An internal long bone fracture fixation device for the treatment of a long bone fracture." No patentable weight appears to have been

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given to this preamble. Applicant submits that the preamble is 'necessary to give life, meaning, and vitality' to the claim. As set forth in the MPEP:

"If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)(In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose.). *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an 'abrasive article.'" Therefore, the preamble served to further define the structure of the article produced.). MPEP §2111.02

The claim preamble of the present invention recites "An internal long bone fracture fixation device for the treatment of a long bone fracture." Analogous to *Jansen v. Rexall Sundown, Inc.*, the recitation of "for treatment of a long bone fracture" gives life and meaning to the preamble's statement of purpose. Similarly, analogous to *Kropa v. Robie*, "internal long bone fracture fixation device" is essential to point out the invention defined by claims to a device comprising a plurality of bone plates and at least one transverse element. It is only by that phrase that it can be known that the subject matter defined by the claims is comprised of an internal long bone fracture fixation device. Therefore, the preamble serves to further define the structure of the article produced.

Roaf relates to spinal stabilizing devices that have nothing to do with internal fracture fixation of a long bone. Roaf includes two like rigid bars 1 and 3 that have a plurality of apertures 5 therethrough. Each aperture 5 has associated with it a slot 19 which extends from the aperture to a common side surface of the relevant bar. A plurality of tapered plugs 21 is provided for location in

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the tapered apertures 5. Each bar also includes two threaded bores 7 for threaded engagement with screws 9 to secure transverse spacer members 11 to the bars. Each bar further includes two further threaded bores 13, respectively adjacent the bores 7, for threaded engagement to secure cover plates 17 to bars 1 and 3.

Two tapes 23 are provided for use with the bars. The first step in implantation after exposure of the site is to pass the tapes in and out of the laminae. The bars 1 and 3 are then brought up to the spine at opposite sides of the spinous processes 25, between the spinous process and the respective transverse process, and are joined together by the spacer member 11. The upstanding end portions of the tapes and the upstanding loop portions are introduced into appropriate aperture 5 of the bars by slipping them through the slots 19. One end portion of each of the tapes is secured to its respective bar by inserting a plug 21 in the aperture 5 through which the end portion extends so as to grip the tape between the plug and the bonding surface of the aperture. The slack in the tapes is worked towards their free, unsecured ends to progressively tighten the tapes from their secured ends. By this action, the vertebrae in the curve are displaced and rotated in contact with the bars and the curve is thereby corrected, and this correction is held by insertion of plugs into the successive apertures through which the tapes extend. The free ends of the tapes above are cut off short and the cover plates 17 are secured to the bars.

One of ordinary skill in the art would understand that Roaf is related solely to the spine and that the spine, either collectively or viewing each of its various components separately, is not a long bone. Even if Roaf were somehow construed to relate to the invention as claimed, Roaf fails to disclose or suggest all of the elements of the present invention. For example, Roaf does not teach or suggest that the bar members include slots or notched segments on a top surface of the bars about the threaded bores.

As previously noted, the present invention discloses a device for the treatment of orthopedic fractures, and more particularly, to the internal fixation of long bone fractures. (¶[0001]). The device 10 includes a first bone plate 12 and a second bone plate 14, each affixable to the cortical surface of a long bone 16. (¶[0023]). The bone plates 12 and 14 are affixed along the longitudinal length and about the circumference of the long bone 16, wherein

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the bone plates 12 and 14 intersect a bone fracture 18. (Id.). The device 10 further includes at least one transverse member 20 affixable to the bone plates 12 and 14. (¶[0025]). At least one of transverse members 20 is affixed to adjacent bone plates 12 and 14, wherein the transverse member 20 spans the radial distance between the bone plates 12 and 14, providing torsional support to the device 10. (¶[0028]). Referring to FIG. 5, the transverse members 20 each include a first end 28, a second end 30, and an intermediate section 32 therebetween that partially spans the circumference of the long bone 16. (¶[0028]).

The bone plates 12 and 14 each include a plurality of screw holes 22, extending therethrough for receiving bone screws 24 to be driven into the long bone 16. (¶[0026]). The bone plates 12 and 14 each include a plurality of threaded holes 26 extending therethrough for attachment of the transverse members 20. (¶[0027]). A transverse member 20 is affixed to the bone plates 12 and 14 by passing the transverse member attachment screw 36 through the screw hole 34 and engaging the threaded holes 26 on the bone plates 12 and 14. (¶[0028]).

The bone plates 12 and 14 also include a plurality of notched segments 38. (¶[0030]). The notched segments 38 are located along the length of the bone plates 12 and 14, such that a threaded hole 26 is positioned within each of the notched segments 38. (Id.) The notched segments 38 are configured for receiving the first and second ends 28 and 30 of the transverse members 20, such that the first and second ends 28 and 30 of the transverse members 20 are recessed within the bone plates 12 and 14. (Id.) The notched segments 38 reduce the overall profile of the device 10, allowing the transverse member 20 to be substantially flush with the top surface of the bone plates 12 and 14. (Id.)

The bone plates 12 and 14 substantially prevent movement of the bone fracture 18 when the long bone 16 is subjected to compressive and tensile forces. (¶[0023]). Additionally, at least one of the bone plates 12 or 14 can be affixed to a lateral side of the long bone 16 to substantially prevent movement of the long bone fracture 18 when the long bone 16 is subjected to bending forces. (Id.) The transverse members 20 substantially prevent movement of the bone fracture 18 when the long bone 16 is subjected to torsional forces. (¶[0025]).

As such, the present invention discloses a long bone fracture fixation device. The device

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includes bone plates which are affixed along the longitudinal length of the long bone, traversing the bone fracture. The bone plates prevent movement of the bone fracture when subjected to compressive, tensile, and bending forces.

Transverse members are affixed and interposed between bone plates. The transverse members have an arcuate shape which spans the circumference of the long bone between the bone plates. The transverse members prevent movement of the bone fracture when subjected to torsion forces. An arcuate transverse member is also not disclosed in Roaf.

The bone plates further include notched segments, each having a threaded hole therein. The notched segments are configured to receive the ends of the transverse member therein for attachment of the transverse members to the bone plate. The notched segments allow the transverse members to be substantially flush with the top surface of the bone plates. Notched segments for receiving the ends of the transverse members are also not disclosed in Roaf.

Furthermore, Applicant submits that Roaf is not analogous prior art. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992).

In the present invention, the inventor's endeavor is towards a long bone fracture fixation device. The device included bone plates and transverse members which are affixed to a long bone, across a fracture. The device prevents movement of the bone fracture when subjected to compressive, tensile, bending, and torsional loading. In contrast, Roaf is directed to a spinal stabilizing device for correcting scoliotic curves and maintaining the correction. The device includes bar members and spacers and is affixed to the vertebrae using tapes. The device allows movement of the vertebrae with respect to the device. As such, the spinal stabilizing devices for correcting scoliotic curves of Roaf are not in the field of the endeavors nor reasonably pertinent to the particular problem with which the inventor was concerned, namely, providing an internal long bone fixation device for preventing movement of a fracture.

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Furthermore, claim 1 recites *inter alia*, an internal long bone fracture fixation device for the treatment of a long bone fracture. The device includes a plurality of bone plates having first and second bone plates affixable along a longitudinal length of a cortical surface of a long bone. The first and second bone plates have a plurality of transverse member attachment holes extending therethrough, each configured for receiving a transverse member attachment screw, and a plurality of notched segments, such that each of the plurality of transverse member attachment holes is positioned within a notch segment. The device further includes at least one transverse member affixable to and interposed between the plurality of bone plates. The transverse member includes first and second ends have a screw hole therethrough for receiving the transverse member attachment screw.

Claim 17, recites *inter alia*, an internal long bone fracture fixation device for the treatment of a long bone fracture. The device includes first and second bone plates affixable to a cortical surface of a long bone along a longitudinal length of the long bone. A plurality of transverse members are affixable to and interposed between the first and second bone plates. The transverse members each have first and second ends and an intermediate section interposed between the first and second end, the intermediate section having an arcuate radius of curvature. The plurality of transverse members substantially prevents a torsional movement of the long bone fracture. Claim 26 substantially includes the elements of claims 1 and 17.

In light of the foregoing, independent claims 1, 17, and 26 are respectfully submitted to be patentable over Roaf. As claims 3-5, 7, 10 and 11 depend from claim 1 and claims 16-21 depend from claim 17, and necessarily include all the elements of their base claims, Applicant respectfully submits that these dependent claims are also patentable at least for the same reasons.

Withdrawn Claims

Claims 13-16 and claims 22-25 were withdrawn from consideration. As provided above claims 1 and 17 are submitted to be patentable over the cited prior art. As claims 13-16 depend from claim 1 and claim 22-25 depend from claim 14, and necessarily include all the elements of their base claims, Applicant respectfully requests rejoinder of the claims and submits that these

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dependent claims are also patentable at least for the same reasons.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No Fee is believed due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 7996-A03-003).

Respectfully submitted,



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